

## **REMARKS**

### **Status of the Claims**

Claims 1-2, 7-9, 15-16, 31-33, 39, 43, 66, 69-70, 77 and 97-106 are pending in the application, claims 14, 48 and 85 being cancelled herein. Claim 7 is withdrawn herein. Claims 1, 15-16, 39, 69, 100, 103 and 106 are amended herein. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

With respect to claims 1, 15-16 and 100, support for stably integrating a nucleic acid segment that encodes a carotenoid biosynthetic polypeptide into a plant cell can be found throughout the specification, e.g., see Examples 1 and 2 in the specification.

With respect to claim 39, support for altering pineapple plant coloration by stably integrating a nucleic acid segment that encodes a carotenoid biosynthetic polypeptide can be found, e.g., at paragraph [0069] in conjunction with Examples 1 and 2 in the specification.

With respect to claims 69 and 106, support for a pineapple cell comprising at least one introduced nucleic acid segment that encodes a carotenoid biosynthetic polypeptide selected from the group indicated can be found, e.g., at paragraph [0039] in conjunction with Examples 1 and 2.

With respect to claim 16, support for a tissue-specific promoter can be found throughout the specification, e.g., at paragraphs [0011] and [0119]

With respect to claim 39 and its dependents, support for altering pineapple fruit coloration is replete throughout the specification, e.g., at paragraphs [0005]-[0006] and [0025].

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested. Applicants traverse all rejections, to the extent that they are applied to the amended claims.

**The Election/Restriction Requirement**

Pursuant to a restriction requirement and telephone conversation between Jonathan Alan Quine and Examiner on May 9, 2008, Applicants affirm the election of Group IV, claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 as they relate to biosynthetic polypeptides of at least one of (iii) a phytoene synthase and (vi) a lycopene beta cyclase. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

**35 U.S.C. §102**

Claims 1-2, 8-9, 39, 43, 66, 69-70, 77, 97-98, 101 and 104 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,952,543, issued September 19, 1999. To the extent that these rejections are applied to the amended claims, Applicants traverse.

Applicants appreciate the Examiner's helpful comments regarding claims that are deemed free of the prior art at p. 11. While Applicants do not concede that claims rejected for alleged anticipation are not novel, in order to facilitate prosecution, the claims are amended herein to cover subject matter deemed free of the prior art in the Action. Accordingly, claim 1 is amended herein to include the limitations of claim 14, claim 39 is amended to include the limitations of claim 48, and claim 69 is amended to include the limitations of claim 85. As all dependent claims depend from claims 1, 39 or 69, all claims as amended are free of the prior art. Accordingly, the rejections for alleged anticipation should be withdrawn.

Claims 1, 9, 39, 43, 66, 69, 77, 97-98, 101 and 104 were rejected under 35 U.S.C. 102(e) as allegedly anticipated by Loison (U.S. Patent PP12,861). To the extent that these rejections are applied to the amended claims, Applicants traverse.

As noted above, the claims as amended are directed to subject matter that the Examiner has helpfully indicated to be free of the prior art. Accordingly, the rejections for alleged anticipation should be withdrawn.

**Non-Statutory Obviousness-Type Double Patenting**

Claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 5, 10, 17, 18 and 21-23 of copending U.S. Patent Application No. 10/536,885.

A rejection based on nonstatutory obviousness-type double patenting can be overcome by filing a terminal disclaimer in the application in which the rejection is made. MPEP §804.02, citing *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Further, the filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Id.*, citing *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991).

While Applicants do not concede that the claims of the instant application are not patentably distinct from those of commonly assigned U.S. Patent Application No. 10/536,885, in the interest of facilitating prosecution, Applicants are willing to file a terminal disclaimer in accordance with 37 C.F.R. 1.321(c) when all other issues concerning the application are resolved, assuming such a disclaimer is still appropriate at that point. The examiner is invited to telephone the undersigned to arrange for submission of the appropriate disclaimer.

Claims 1-2, 8-9, 39, 43, 66, 69-70, 77, 97-98, 101 and 104 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 5,952,543. Applicants traverse.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). MPEP §804. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Three requirements must be met to establish a prima facie case of obviousness. First, the prior art reference(s) must teach all of the limitations of the claims.

MPEP §2143.03. Second, there must be a common sense rationale to modify the reference or combine the teachings to produce the claimed invention. MPEP §2143.01. Third, a reasonable expectation of success is required. MPEP §2143.02. The teaching or suggestion to combine and the expectation of success must be both found in the prior art and not based on Applicants' disclosure. MPEP §2143. These requirements were reaffirmed in *KSR v. Teleflex*, 550 U.S. \_\_\_, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007).

The Action alleges that the claims 1-2, 8-9, 39, 43, 66, 69-70, 77, 97-98, 101 and 104 of the instant application are not patentably distinct from claims 1-38 of U.S. Patent No. 5,952,543, because the “transformation of pineapple using embryogenic callus and the broadly-claimed *etr*-like genes is obvious over the broad instant claims drawn to carotenoid biosynthetic polypeptide expression regulators . . . .” Applicants disagree with the Action’s allegation, at least because the claims of the cited reference, in conjunction with the art, do not include all of the claim limitations of the instant application. Even when given its broadest possible interpretation, modifying the genotype of a pineapple cell with a DNA segment derived from an *etr*-related gene, as provided in claim 6 of the cited reference, is not relevant to controlling carotenoid accumulation in pineapple. *Etr*-related genes encode proteins that mediate a plant’s cellular response to ethylene. Responses to ethylene are relevant to the ripening, and possibly the alteration of carotenoid levels, of climacteric fruits, e.g., tomatoes. In contrast, ethylene is not produced during the ripening of non-climacteric fruits, e.g., pineapple, bell pepper, etc. *Etr*-related genes, therefore, play no role in the ripening, or accumulation of carotenoids that accompanies ripening, of pineapples. Accordingly, carotenoid biosynthesis and accumulation in pineapples is completely independent of ethylene/ethylene responses. The cited reference teaches the transformation of pineapple cells with *etr*-related genes, but does not teach a method of controlling carotenoid accumulation in pineapples. Because, e.g., this limitation is absent from the cited reference, it does not render obvious the claims of the present invention, and the rejection must be withdrawn.

The second requirement for establishing a *prima facie* case of obviousness – a common sense rationale to modify the reference or combine the teachings to produce the claimed invention – is not met. First, “rejections on obviousness cannot be sustained by

mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396. The Action provides no articulated reasoning to support a finding of obviousness. Rather, the Action merely states on page 10 that "the transformation of pineapple using embryogenic callus and the broadly claimed *etr*-like genes is obvious over the broad instant claims drawn to carotenoid biosynthetic polypeptide expression regulator that controls accumulation of carotenoids in pineapple." Second, a common sense rationale does not exist to combine the teachings of claim 6 of the cited reference with the general state of the art. As noted above, ethylene responses, and hence *etr*-related genes, are independent of carotenoid accumulation in non-climacteric fruits such as pineapple. For this reason alone, there is no common sense rationale to modify the reference or combine the teachings to produce the claimed invention, i.e., one of skill would not think to combine the transformation of pineapple with *etr*-related genes with the general state of the art to produce the claimed invention, because *etr*-related genes play no role in carotenoid accumulation in pineapple. For this reason as well, the second requirement for establishing a *prima facie* case of obviousness is not met, and the rejection should be withdrawn.

A *prima facie* case of obviousness also requires a reasonable expectation of success. Because *etr*-related genes are not relevant to fruit ripening or carotenoid accumulation in pineapple, one of skill would not expect the transformation of pineapple with *etr*-related genes to alter carotenoid accumulation in pineapple. Accordingly, a reasonable expectation of success is absent and the rejection should be withdrawn.

### **35 U.S.C. §112, First Paragraph**

Claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. To the extent that these rejections are applied to the amended claims, Applicants traverse.

The "written description" requirement has been formulated in a number of ways over the years. One relatively clear, current and concise statement of the written description requirement set forth by the Federal Circuit is as follows:

“The [written description] requirement may be satisfied if the claim terms ‘readily convey distinguishing information concerning their identity, such that one of ordinary skill in the art could visualize or recognize the identity of a member of the genus.’ *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 65 USPQ2d 1385 (Fed. Cir. 2003).

The Action alleges that the claims fail to comply with the written description requirement because the “[a]pplicants fail to describe a representative number of nucleic acid segments that are homologous to or correspond to the endogenous polynucleotide encoding phytoene synthase or lycopene beta cyclase in pineapple.” See the Action at p. 5.

Applicants disagree with the Action’s allegation. First, the claimed invention does not require the use of nucleic acid segments derived from pineapple to control carotenoid accumulation in pineapple. Support for the use of heterologous nucleic acid sequences to control carotenoid accumulation across species is replete throughout the specification. As just one example, overexpression of phytoene synthase genes from the genus *Erwinia*, described in the specification at, e.g., paragraph [0077], results in a 2- to 4-fold increase in total carotenoid levels in transgenic tomato fruits. (Fraser P. et al., P.N.A.S. Vol. 99 No. 2 (2002), pp. 1092-1097, see Table 1 at p. 1095). Further, “golden rice,” where expression in rice of phytoene synthase nucleic acid sequences derived from daffodil (*Narcissus pseudonarcissus*) results in altered coloration of the rice grains. (Ye X. et al., Science, Vol. 287, pp. 303-305, see Figure 2 at p. 305). These are just two representative examples of how heterologous nucleic acid sequences have been employed to control carotenoid accumulation across species. The specification describes a number of such nucleic acid sequences that encode carotenoid biosynthetic polypeptides, e.g., see Section IV beginning at paragraph [0075], where representative nucleic acids encoding each of the carotenoid biosynthetic polypeptides of the claimed invention are described.

In addition, carotenoid biosynthesis genes exhibit nearly 80% sequence identity at the amino acid level across plant species. This extraordinarily high level of similarity among carotenoid biosynthetic polypeptides readily permits one of skill to visualize or recognize the identity of a member of the genus of the claimed invention. On this basis and for the reasons noted above, Applicants’ specification thoroughly describes the

nucleic acid sequences of the claimed invention. Accordingly, the rejections for failing to comply with the written description requirement must be withdrawn.

Claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. To the extent that these rejections are applied to the amended claims, Applicants traverse.

To be an enabling disclosure under §112, first paragraph, a patent must contain a description that enables one skilled in the art to make and use the claimed invention. That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive. See *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The Action alleges that the specification does not meet the enablement requirement because “Applicants do not teach polynucleotides that are homologous to the endogenous pineapple carotenoid biosynthetic genes; plants thereof or methods thereby.” Action at p. 7. Applicants disagree with the Action’s allegation. As noted above, heterologous nucleic acid sequences encoding carotenoid biosynthetic polypeptides have been widely employed across species to modulate carotenoid accumulation. Applicants teach representative nucleic acid sequences that encode each of the carotenoid biosynthetic polypeptides of the claimed invention, e.g., see Section IV beginning at paragraph [0075]. The specification teaches in great detail methods for transforming and selecting pineapple cells and plants with such nucleic acid sequences, e.g., see Example 1 beginning at paragraph [0166].

The Action cites Bramley et al. (The Plant Journal; 1992, Vol. 2 No. 3, pp. 343-349) as supporting the assertion that the use of heterologous nucleic acid sequences yields unpredictable results in antisense applications. Applicants note that, in the event that a nucleic acid sequence described in the specification does not produce the desired result in pineapple (which Applicants do not concede would happen), such sequences are readily optimized using recombinant DNA techniques. Further, since modulation of carotenoid levels according to the claimed invention alters pineapple plant coloration, the efficacy of a particular nucleic acid for achieving the desired result is readily determined by visual

inspection of the transformants. For these reasons, the level of experimentation required to make and use the claimed invention is not unduly extensive. Accordingly, Applicants have provided an enabling disclosure and the rejections should be withdrawn.

### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 50-0893.

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Respectfully submitted,



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Attachments:

- 1) A transmittal sheet;
- 2) A fee transmittal sheet;
- 3) Information Disclosure Statement
- 4) PTO-1449 Form;
- 5) 2 References; and
- 6) A receipt indication postcard.